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10/587,728	03/26/2007	Frank Rothbrust	FI-80PCT	2019

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EXAMINER	
ROYSTON, ELIZABETH	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/587,728	**Applicant(s)** ROTHBRUST ET AL.	
	Examiner Elizabeth Royston	**Art Unit** 1747	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-21 and 40-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-21, and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 4-15, 17, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. 2001 in view of Hansen (WO 95/35070), Martin (WO88/02742), and Glass (US PN 5478785).

With regard to claims 1, 5-7, 17, 41, and 42, Lin teaches a process for producing a ZrO_2 containing inorganic-inorganic composite having a biaxial strength of not less than 800 MPa (Table III, Hardness values) comprising the steps of producing an open-pore blank of ZrO_2 powder by pressing (page 71, col. 2, section II(1), line 15-18), pre-sintering the blank (page 71, col. 2, section II(1), line 21-22), applying an infiltration substance which comprises a precursor of a nonmetallic-inorganic phase, or an

amorphous glass phase and a solvent, or of a hydrolysable compound of a metal, or contains an alkoxide of a metal, or a precursor of a silicate glass to said shaped part (page 72, col. 2, section II(2), line 1-11) at room temperature (page 72, col. 2, section II(3), line 2), carrying out penetration of the infiltration substance into the blank (page 72, col. 1-2, section II(3)), sintering the blank in a densifying manner under in static air (page 72, col. 2, section II(4), line 1-5, interpreted to read on a static atmospheric environment, and therefore at ambient pressure).

Lin does not explicitly disclose infiltrating under vacuum.

Martin teaches that infiltrating under vacuum gives infiltration times of 10 to 15 minutes (page 6, line 17-28) and that vacuums of less than 40 mbar were known in the art at the time of the invention (page 10, line 14-15). Furthermore, Glass teaches that the time of infiltration (, including vacuum infiltration (col. 3, line 49), is a result effective variable dependent upon the desired depth of infiltration (col. 6, linen 35-37) and the physical properties of the alkoxide of a metal infiltrant (col. 5, line 1-15; col. 6, line 61) and zirconia preform (col. 3, line 50-61; col. 6, line 5-7). It would have been obvious to one of ordinary skill in the art at the time of the invention to use vacuum infiltration during the infiltration in the teaching of Lin. The rationale to do so would have been the motivation provided by the teaching of Martin, that to use such vacuum infiltration predictably results in the successful infiltration of the preform in a desired time frame (page 6, line 17-18). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the time of infiltration as based upon the

desired depth of infiltration and the physical properties of the infiltrant and preform as in the teaching of Glass.

Although Martin does not explicitly disclose a vacuum of 10 to 30 mbar, since the force of vacuum is tied directly to the infiltration method, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the vacuum based upon the physical properties of the infiltrant and preform so that the desired depth of infiltration was achieved.

Lin does not explicitly disclose a density of greater than 99.5%. However, Lin does teach that the infiltration increases the final density (page 77, col. 2, section III(5), lines 4-5) and that the success of infiltration is dependent on the porosity of the preform (page 78, col. 1, section IV, line 5-7). Furthermore, Glass teaches that the final density is a result effective variable dependent upon the sintering temperature and time of sintering (col. 6, line 48-50; col. 7, line 45-48, e.g. the increase of 50°C in the sintering temperature decreases the time required for achieving a similar final density by 10 hours), infiltrant, and porous preform (col. 6, line 54-60) used, and that densities of >99.5% for zirconia-based preforms were known in the art at the time of the invention (col. 4, line 58-59, col. 6, line 54). It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the time and temperature of sintering and the infiltration amount of the body in the method of Lin so as to achieve a desired final density of the product.

Lin does not explicitly disclose creating a translucent dental restoration or debinding.

Hansen teaches a method of making a ZrO_2 containing (page 4, line 11-12) dental restoration (page 1, line 2-6) comprising the step of debinding a binding agent prior to presintering (page 4, line 27-28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a binding agent and to debind the bonding agent prior to infiltration. The rationale to do so would have been the motivation provided by the teaching of Hansen, that to have such a binding agent and debinding method predictably results in the formation of a shaped structure (page 4, line 18-26) suitable for use in a ceramic tooth (page 1, line 2-6). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to shape the blank after sintering. The rationale to do so would have been the motivation provided by Hansen, that to shape after sintering predictably results in the ability to remove the excess glass (page 4, line 37).

Although Hansen does not explicitly disclose that the material is translucent, since the material is being used as a dental restoration, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a material that matches the appearance of regular teeth. Furthermore, since the material in the teaching of Lin contains a ZrO2 preform infiltrated with an aluminum nitrate and TEOS infiltrant, the same materials as claimed by applicant, the material in the teaching of Lin must have intrinsically been translucent.

Lin does not explicitly disclose shaping the blank after sintering with milling or etching.

Hansen teaches shaping the blank after sintering (page 4, line 37-39)

Although Hansen is silent as to the exact method of removal and does not explicitly disclose milling or etching, since material is successfully removed from the body, it would have been obvious to one of ordinary skill in the art at the time of the invention to use conventional removal techniques such as milling or etching to remove the material.

With regard to claim 4, Lin teaches that the presintering takes place at a temperature of from 900-1100°C.

With regard to claims 8-12, although Lin teaches that the success of infiltration is dependent on the porosity of the preform (page 78, col. 1, section IV, line 5-7), Lin does not explicitly disclose an infiltration layer thickness of 10 to 90% of the pre-sintered open-pore crystalline oxide ceramic thickness. However, Glass teaches that the infiltrant layer thickness is dependent only on time (assuming consistent pore size in the pre-sintered ceramic and viscosity of the infiltrant), in a known relationship (col. 5, line 9). Therefore, the layer thickness of the infiltrant relative to the thickness of the preform is dependent on the initial size of the preform and the calculated time of infiltration. It would have been obvious to one of ordinary skill in the art to adjust the time of infiltration in the teaching of Lim so that the layer thickness was between 10 to 90% of the thickness of the pre-sintered open-pore crystalline oxide ceramic.

Furthermore, although Lin does not explicitly disclose an infiltration layer thickness between 5 and 20% of the sintered composite material, since Glass teaches that some shrinking of the composite occurs upon sintering (col. 5, line 34-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the infiltration thickness on the preform to account for such shrinkage such that the final sintered composite would have an infiltrant layer thickness from 5 to 20% of the sintered composite material.

With regard to claims 13-15, Lin teaches a polar ethanol solvent (page 72, col. 1, section II(2), line 1).

With regard to claim 40, Lin teaches yttrium oxide (page 71, col. 2, section II(1), line 1, yttria).

4. Claims 16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. 2001 in view of Hansen (WO 95/35070), Martin (WO88/02742), and Glass (US PN 5478785), as applied for claims 1, 4-15, 17, and 40-42 above, and further in view of Tyszblat (US PN 5447967).

With regard to claim 16, Lin in view of Hansen, Martin, and Glass does not specifically disclose machining prior to infiltration.

Tyszblat teaches that machining of dental restorations prior to infiltration (col. 3, line 42-43) was known in the art at the time of the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to machine the ceramic in the teaching of Lin in view of Hansen, Martin, and Glass prior to infiltration. The rationale to do so would have been provided by the motivation found in the teaching of Tyszblat, that to shape the un-infiltrated ceramic predictably enables a better control over the final shape of the ceramic, for example the fit of an artificial tooth (col. 2, line 65-68; col. 3, line 11-13).

With regard to claims 20 and 21, Glass in view of Jones does not explicitly disclose an oversize of 15 - 30%.

Tyszblat teaches the removal of material to shape a preform to the desired configuration (col. 3, line 42-43; col. 3, line 59-60).

Although Tyszblat does not explicitly disclose a specific oversize for the product at any step, it would have been obvious to one of ordinary skill in the art at the time of the invention to include sufficient oversize in the initial preform optimized such that the desired final shape and size of the product can be achieved through machining by removing product (i.e. sandblasting col. 5, line 13).

5. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. 2001 in view of Hansen (WO 95/35070), Martin (WO88/02742), and Glass (US PN 5478785), as applied for claims 1, 4-15, 17, and 40-42 above, and further in view of Kondo (US PN 4626392).

With regard to claims 18 and 19, Lin in view of Hansen, Martin, and Glass does not explicitly disclose attaching at least a one-layer coating of a further material to the surface of the composite material or subjecting the layered composite and further material to heat treatment.

Kondo teaches attaching an additional layer of a further material to the surface of the composite material and subjecting the layered composite and further material to heat treatment (col. 3, line 55-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the additional layers taught by Kondo to the process for making a composite material taught by Lin in view of Hansen, Martin, and Glass. The rationale to do so is the motivation provided by the teaching of Kondo, that to include the layer of a further material predictably produces ceramic materials suitable for surgical implantation (col. 3, line 50-53).

6. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. 2001 in view of Hansen (WO 95/35070), Martin (WO88/02742), and Glass (US PN 5478785), as applied for claims 1, 4-15, 17, and 40-42 above, and further in view of Beesabathina (US PN 6071622).

With regard to claim 43, although Lin teaches an infiltration substance including TEOS and aluminum nitrate (page 72, col. 2, section II(2), line 1-5), Lin does not explicitly disclose cerium nitrate.

Beesabathina teaches that the addition of cerium nitrate to TEOS (also known as tetraoxysilane) is known to stabilize glass composites (col. 11, line 18-19, 26-31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add cerium nitrate to the infiltrant in the teaching of Lin. The rationale to do so would have been the motivation provided by the teaching of Lin, that to add cerium nitrate predictably results in a glass with low solubility that is resistive to corrosive environments (col. 10, line 15-24).

Response to Arguments

7. Applicant's arguments filed 10/7/2010 have been fully considered but they are not persuasive.

With regard to applicant's argument that Lin teaches a maximum theoretical density of 98%, the examiner agrees. However, with the conclusion that applicant then draws that it would not have been obvious to one of ordinary skill in the art at the time of the invention to know that densities of at least 99.5% were possible in such preforms, the examiner respectfully disagrees and respectfully reminds applicant that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's dismissal of the teaching of Glass on page 14 of the response filed 10/7/2010 is not warranted, as Glass is relied upon to teach that theoretical densities of sintered zirconia-based ceramics above 99.5% were known in the infiltration art (col. 4,

line 59, 67), and that for an aluminum nitrate infiltrated zirconium oxide preforms specifically, such as the preform in the teaching of Lin, densities of greater than 99% were possible (col. 6, line 53-54), overlapping with applicant's claimed density range. Furthermore, Glass teaches that such densities are also achieved through a process of multiple infiltrations (col. 6, line 22), such as in the teaching of Lim, and that a process of infiltration can be aided by using vacuum infiltration (col. 3, line 45-50). It is the teaching of Glass that demonstrates that vacuum infiltration was known in the art at the time of the invention in relation to infiltrating a zirconium preform and that using such measures can aid in the infiltration of the preform. Martin is relied upon solely to teach method of infiltrating a ceramic preform, as the materials have been previously disclosed by Lin and the motivation to do so disclosed by Glass. Therefore, while the examiner agrees that the teaching of Martin does not disclose the same preform and infiltrant composition as claimed by applicant, it is the examiners position that the material properties of a pressed powder ceramic and a liquid infiltrant under vacuum are similar enough to render the infiltration method of Martin within the same field of endeavor as the vacuum infiltration method in the teaching of Lin in view of Glass.

However, the examiner does note that the teaching of Lin in view of Glass does not disclose a theoretical density that applies to the situation of a sol-infiltrated zirconia preform, only to the solution infiltrated zirconia preform.

With regard to applicant's argument that the teaching of Hansen can not be combined with the teachings of Lin in view of Martin and Glass, the examiner

respectfully disagrees. While the examiner agrees that the method of forming the final infiltrated product is not the same between the teaching of Hansen and the teachings of Lin in view of Martin and Glass, Hansen is relied upon to teach that glass-infiltrated ceramic preforms were known in the dental art at the time of the invention as suitable for use as artificial teeth and that in such applications, binder is not desirable in the final product. Therefore, since a zirconia ceramic-glass infused product was known in the art at the time of the invention as suitable for use as an artificial tooth, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the zirconia ceramic-glass infused product in the teaching of Lin in view of Martin and Glass in such an application, and to furthermore optimize the product so that it was acceptable for use in such an application.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Royston whose telephone number is 571-270-7654. The examiner can normally be reached on M-F 9:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. R./
Examiner, Art Unit 1747

/Richard Crispino/
Supervisory Patent Examiner, Art Unit 1747